



NEW APPROACHES for procuring **effective healthcare solutions**





Forward

This White Paper is being published by IMSTA, the representative body for medical technology supply companies in Ireland.

IMSTA is a member of GMTA, the Global Medical Technology Alliance whose members are national or regional medical technology associations which represent innovative companies that currently develop and manufacture 85 percent of the world's medical devices, diagnostics and equipment. It provides a forum for the development and advocacy of policies that support innovation in medical technology to address patients' healthcare needs.

IMSTA member companies in Ireland include the full spectrum of medical technology supply and service companies from SMEs to MNCs, many of whom have R&D and/or manufacturing facilities in Ireland.

IMSTA member companies provide highly trained clinical professionals, biomedical / clinical engineers and medical scientists to support the medical technology in use in the Irish health service. They provide training for clinicians, nurses, biomedical and clinical engineering and other health care professionals in the application and use of innovative medical technologies.

This paper is being published with the kind permission of the Advanced Medical Technology Association (AdvaMed). It reflects the second stage of a consultation between industry and government procurement stakeholders. The first stage occurred at an International Innovation Procurement Roundtable in Toronto in December 2013 and also resulted in a White Paper. The goal of the Second International Innovation Procurement Roundtable in Barcelona in June 2014 was to distill further and refine and translate the discussion from both conferences into specific recommendations for good tendering practices. Participants and Observers are listed on Page 39.

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Introduction

The importance of innovation and value in medical device procurement

The procurement of effective healthcare solutions is one of the most pressing public policy issues for the vast majority of countries. Health and finance ministries have to balance the need for sustainable health systems in the context of an aging population and increasing demand for health care services against the challenges of limited budgets and dwindling public resources.

Introduction

In the summer of 2011 IMSTA, in partnership with Enterprise Ireland, commissioned Dublin City University to carry out a review of current procurement practices for medical supplies/technologies.

The objective of the study was to review current procurement practices and to make recommendations for best practice. The review of current procurement practices was based on two approaches, an overview of the current literature and international practice of procurement and a review of current practices in Ireland.

The research revealed that procurement within the public sector is seen as more a traditional tendering role rather than a set of activities that can contribute more than the tender itself. The full range of the procurement process is not being utilized. In many cases of procurement in the public sector, engagement with suppliers either through pre-market engagement or through ongoing contract evaluation does not take place.

In 2013 / 2014 work has been carried out by the Advanced Medical Technology Association (AdvaMed) on good practices for the procurement of innovative medical technology. This has led to this report being compiled and now published by IMSTA as a supplement and in addition to the previous work carried out in 2011.

Deciding which healthcare technologies to procure, and how to procure them is still an ongoing policy dilemma. In a continuing environment of budget constraints, innovative and high-value technologies can be marginalized. This can lead to an exaggerated focus on commodity purchasing, whereas outcome based purchasing should be the aim.

This updated paper aims to offer a set of comprehensive guidelines to equip healthcare system stakeholders with proven practices that support smarter procurement. The overriding purpose of these guidelines is to make recommendations for effective healthcare tendering to promote the procurement of innovative products, services and delivery models, to achieve greater value for money and ensure that limited public resources are spent wisely. An informed focus on innovative, constantly evolving technology, procured with a full awareness of societal benefits and healthcare outcomes, is a critical factor in sourcing successful healthcare solutions.

This paper reflects consultations between industry and government procurement stakeholders from an international environment. The purpose of this paper is to be expressly prescriptive. It represents action points that should be actively adopted by procurement agencies and should form part of a national protocol for the procurement of innovative healthcare technologies.

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December 2014

An informed focus on innovative, constantly evolving technology, procured with a full awareness of societal benefits and healthcare outcomes, is a critical factor in sourcing successful healthcare solutions.

Innovation

What is innovation?

Innovation is about finding new approaches – including new technology as well as new applications of existing technology, and new models for services and solutions - in order to improve patient outcomes, enhance efficiency, or extend the reach of care.

Innovation is about value creation. An idea that is not transformed into some form of social or economic value is not considered innovation. Within the healthcare system, innovation can improve the quality and efficiency of health services, thus contributing to improved population health (social value). For example, innovation can decrease waiting times, length of hospital stays, morbidity and mortality. In addition to obvious social and patient care benefits, innovation also contributes to the affordability of healthcare services (economic value), a major challenge in healthcare systems.

Value

What is value?

Value can be defined as patient health outcomes per unit of currency spent. Value, therefore, encompasses both cost and non-cost factors. The list of features which could contribute to a device's value will vary from case to case, but we list here some of the most typical features of value.

Value encapsulates **cost-related factors which go beyond the initial purchase price**. These cost factors are life-cycle costs and costs relating to ownership and include:

- direct medical costs., e.g. laboratory or diagnostic tests, provider services (including physicians and allied caregivers), as well as hospitalization and sub-acute care.
- costs of maintaining, cleaning, and storing the device. Other ongoing operating costs, including efficiencies achieved in other areas due to introduction of the device.
- upgrade costs.
- staff training and other employment costs.
- disposal costs.

Equally important are **factors associated with patient outcomes or those involving total budget savings**. All of the following should form part of the value assessment of a medical device:

- delivery efficiencies.
- technical benefits/merits.
- safety, i.e., ability to lower or minimize adverse events or complications.
- clinical effectiveness, including reductions in morbidity or mortality or as measured by patient-reported outcomes and patient satisfaction and preference.
- reliability and service level of the vendor/manufacturer, including warranty, maintenance, customer care and clinical training and support.
- societal benefits, e.g. improved patient quality of life, reduction in spend outside the health budget (i.e. productivity and social care gains due to fewer

Value

What is value?

Value can be defined as patient health outcomes per unit of currency spent. Value, Value-based purchasing means procuring medical devices with reference to healthcare outcomes and not merely to satisfy technical requirements. Value is not just about cost, but also and principally about the broader patient health and societal benefits conferred by a medical device. To achieve value, procuring authorities should focus on spending well, rather than spending less.

Value is a holistic concept which covers all aspects of a device's expected impact on healthcare outcomes, recognising that financial, clinical and societal factors are, in almost all cases, important features of a value assessment and on an equal footing with cost factors. The cost analysis itself should go beyond price and take into account life-cycle costs and the broader efficiencies which may be generated by sourcing high-value products – even a device with a high initial price could well end up saving money when its overall economic and clinical context is considered.

Value is a holistic concept which covers all aspects of a device's expected impact on healthcare outcomes, recognising that financial, clinical and societal factors are, in almost all cases, important features of a value assessment and on an equal footing with cost factors.

The terminology for the procurement process that attempts to account for some of the factors beyond initial purchase price, or non-price factors, varies from jurisdiction to jurisdiction. The standard term, as promoted by the United Nations and by a number of national jurisdictions, is the principle of “best value for money.” In the European Union, the term is “most economically advantageous tender” (i.e. MEAT). Both these terms mean a broad and all-encompassing focus on value in opposition to a narrow focus on cost. For instance, the United Nations' procurement division defines “best value for money” as “the optimisation of whole life costs and quality needed to meet user requirements, while taking into consideration potential risk factors and resources available”, which means that price alone is not necessarily determinative of best value. In fact, these terms and practices have come into existence and greater prevalence as jurisdictions have had to come to terms with the negative results of procuring solely on lowest price.

Assessment of the value of a medical device needs to account for the following crucial information inputs:

- **From whose perspective is the technology being evaluated?** Jurisdictions vary in their preferred perspective, e.g. social payer, provider, health authority or fund.
- **What is the pace of innovation for the device category?** Many device categories go through rapid and frequent incremental improvement, involving lower risk and faster development cycles than drugs, with relatively few break-through leaps in innovation. Pharmaceuticals may be the model for some procurement teams and may, in most cases, be a mistaken benchmark.
- **Does the device allow reduced expenditure on other healthcare products and/or services?** Some innovative devices may offer a system solution which may simplify or eliminate related procedures and their associated expense.
- **Do the assessment of innovation and the medical context include the opinion of clinicians who use the devices?** This is also covered in the next section on Health Technology Assessments (HTAs).

Guidance

The paper provides guidance on five key areas.

- Part 1 The importance of innovation in public procurement policy** summarizes the budgetary dilemmas facing procurement decision-makers and explains how a healthcare system approach, encapsulating innovation and value, can bring benefits to medical device procurement.
- Part 2 The pre-tender phase** explains why and how the role of innovation and value should be addressed before specific procurements begin. A thorough needs assessment process resulting in a clear set of requirements is the most important stage in the procurement cycle for innovative products. This section explains how pre-tender market engagement and consultation with Key Opinion Leaders (KOLs), other stakeholders and even government officials can be instrumental in achieving successful procurement outcomes.
- Part 3 Choice of procurement approach** sets out the forms of the approach to the procurement, including procedures which allow for negotiation and dialogue and which therefore may be suited to complex procurements involving innovative products.
- Part 4 Value** defines value in the context of the procurement of medical technology and explains how it can be implemented in procurement processes.
- Part 5 Post-award** explains the considerations that should be taken into account during the lifetime of contracts.

Parts two through five contain recommendations regarding how innovative technology procurement can be used to secure better healthcare outcomes through appropriate analysis of best value.

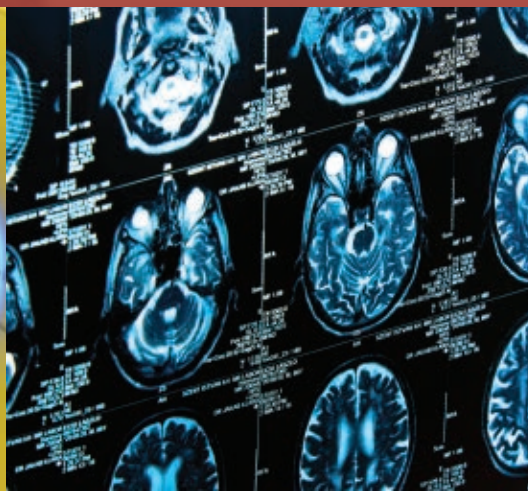
The recommendations seek to:

- increase the awareness and knowledge of procuring authorities about the technology they are procuring and market developments.
- emphasize the importance of value and broader policy objectives beyond solely price.
- emphasize the need to take a holistic approach to a procurement process.
- encourage competition and broad participation in tenders, including by innovative SMEs.

Part

One

The importance of
innovation in public
procurement policy



Part One

The importance of innovation in public procurement policy

Governments have a variety of policy imperatives which influence the procedures they implement in order to meet their healthcare procurement needs. These include the following:

- Greater societal expectations about better healthcare outcomes and accountability for results have been a major driver of recent policy reforms in the delivery of healthcare.
 - An aging population requiring a greater range of ever improving healthcare services.
 - Attempts to address segments of the population that may be “under-served” by healthcare.
 - Against the background of demands for extending and improving care, virtually all governments face rising healthcare spending as a share of GDP, and need to improve efficiency, cost-effectiveness and productivity in order to manage costs.
 - Societal and environmental factors demanding greater sustainability in health systems.
 - Legal risks, including the need to procure ethically and in accordance with procurement law and regulatory requirements, as well as allowing fair access to SMEs.
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The right procurement strategy can help governments thread the best pathway through these sometimes conflicting challenges. Harnessing innovation provides the means to obtain “value” from the investment in healthcare. More specifically, innovation can deliver better patient outcomes through new technologies and treatments; it can bring more efficient ways to organize and manage care; and it can find avenues to extend care to under-served segments with novel technologies or service methods.

Harnessing innovation has the potential to slow the growth in cost of care and improve the health, well-being and economic productivity of the population. In contrast, a focus only on lowest purchase price may not yield such “value” from the tender. Instead, an emphasis on “best” price may result in ineffective, unsuitable or lesser utility solutions that have a weaker impact on health outcomes and miss broader cost savings or efficiency gains.

Harnessing innovation to obtain value in this way is more complex than looking only at price. Four Key principles are reflected throughout these guidelines:

Part One

The importance of innovation in public procurement policy

The pre-tender process is critical for designing the tender to achieve “value for money” for the healthcare system.

Principle 1 A “system” perspective

Tendering to achieve “value for money” requires looking at the health outcomes and efficiencies at the healthcare system level. An intervention that is performed now may extend the life of the patient or reduce complications or the need for additional treatments later. From the perspective of a short-term hospital or payor budget, such intervention may not seem cost-effective in the short-term since the benefits will occur later in time or elsewhere in the healthcare system. In contrast, taking the perspective of the healthcare system as a whole allows consideration of benefits for different care settings and over the lifetime of the patient. Taking into account the broader social care budget expands the savings even further, as patients may be in a position to return to work sooner with less disability and a reduced need for support payments. Since the main concern for most governments is cost and outcomes of the overall system, it seems sensible to analyze “value for money” at a system level for medical technology tenders.

Principle 2 Active engagement and consultation during the pre-tender process

The pre-tender process is critical for designing the tender to achieve “value for money” for the healthcare system. The pre-tender phase involves research to understand the market and the technology applicable to the healthcare issues, the process for engaging stakeholders, and the design of the decision-making criteria and process. Care and rigour at this phase sets the stage for the balanced evaluation of opinions and data necessary for the best judgement of value for money. This is discussed fully in Part Two.

Principle 3 A balanced approach to data

Definitive data may not always exist which allow for the precise differentiation and demonstration of outcomes and costs for particular interventions across the healthcare system. In many instances, evidence may require a choice among available, rather than definitive, options. The broad diversity, rapid innovation cycle and unique nature of medical devices presents a challenge for gathering comparative clinical and health-economic data on all products. On the other hand, manufacturers are steadily increasing their investment in health-economic studies to help support good “value for money” decisions. Yet, excessive or strict demands for health-economic data may slow or reduce innovation and raise barriers for SMEs.

Tendering officials should take a balanced approach using health-economic data such as HTAs to judge “value for money” in medical device tendering. HTAs that examine costs and benefits at the system level better suit the “value for money” objective for the healthcare system as whole. However, it is important to understand the limits of such data and to understand its interpretation and use.

Part One

The importance of innovation in public procurement policy

It is important
Tender decisions for
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of health-
economic data.**

HTAs typically evaluate a solution based on the quality and amount of data to which they have access, and those data may not be fully representative. Studies which examine costs and benefits only at the hospital level may be commercially useful for the hospital but will not necessarily address the impact on the broader healthcare system. Including other stakeholder experiences (e.g. clinicians, patients and hospitals) whenever possible will result in important inputs to fill gaps in HTA data.

In addition to careful evaluation of health-economic data, tender decisions for innovative medical technologies should incorporate expert clinician input. This is important since health-economic data may not exist to answer all relevant questions of “value for money” for the broad range of fast-changing medical technologies.

Principle 4 The importance of selecting an appropriate procurement approach

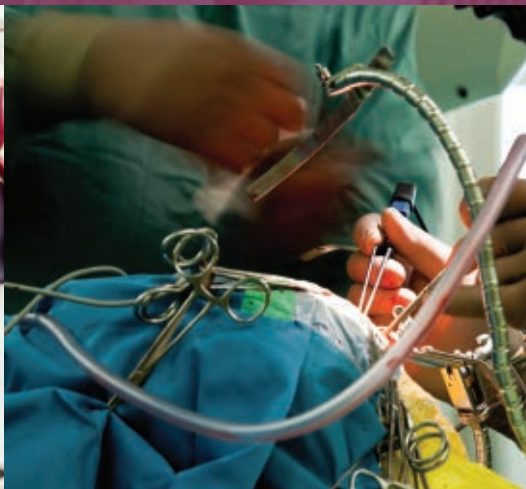
Finally, the procurement approach is important. The following views express current best practices that should be adopted to the procurement approach:

- During the tender procedure itself, procurement authorities should not be afraid to use negotiation-based procedures (or holistic solution-based procedures) where relevant laws permit such procedures and where they fit the nature of the product.
- Large, winner-takes-all procurements could limit the involvement of SMEs in the sourcing of healthcare technology.
- Procurement specifications should routinely contain reference to innovative options, since incremental innovation is an integral part of the device industry.
- It is important to comply with relevant laws, but legal risks should be assessed on a reasonable and pragmatic basis in the light of ongoing developments in applicable regimes. For instance, the newly reformed EU procurement rules show an increasing acceptance of consultations with industry before procurements.

Part

Two

The pre-tender phase



Part Two

The pre-tender phase

Key learnings summary

- Successfully procuring innovative technology requires clear processes to identify needs and early engagement with the market.
 - For medical device procurement, the most important stage is the pre-tender phase. The procurement will only obtain the best-value innovative technology if the specification is drafted to catch it, and a balanced evaluation process is in place to judge it. The key is to work out what you want, before you ask yourself how to get it or how much to pay for it.
 - To produce appropriate specifications, thorough research should be conducted at a sufficiently early stage to identify both those products which are available on the market currently and those products which are expected to be available in the near future.
 - KOLs with clinical experience of using relevant technology should play a central role in drafting specifications.
 - Specifications should be drawn up by a diverse and multi-disciplinary committee.
 - Procurement teams should sense-check all HTA information, and other economic and market research information, with the KOLs on the procurement committee.
 - Procurement teams should be trained on handling legal risks, above all where tenders are subject to procurement law regimes. Part of that training should be to make teams aware that pre-tender discussions which follow a few simple guidelines are legally compliant in many jurisdictions.
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Timing and process – plan early and ensure proper readiness to go to market

The timescales in medical device procurements are driven by a variety of factors. Aside from the need to re-procure to coincide with the termination of existing supply arrangements, factors include a clinical need to source additional technology, changes to service delivery structures and the need to comply with the relevant periods set out in regulated procurement processes. However, it is frequently the case that procurement outcomes can be compromised by constrained timescales and inadequate planning.

Typically, planning for a tender and the preparation of procurement specifications for healthcare technology should commence between 12 and 24 months before initiation of the tender. This allows for a thorough assessment of the organisation's needs, engagement with KOLs, as well as a review of the potential supplier base. However, procuring authorities should also be mindful of the rapid innovation cycle of medical devices and should retain flexibility during the process to allow consideration of the latest technology when the tender is formally commenced.

Part Two

The pre-tender phase

Identifying, in good time, the future needs for medical technology will shape the procurement strategy for procuring authorities.

Needs assessment – establish a clear understanding of the required outcomes and clinical needs

Identifying, in good time, the future needs for medical technology will shape the procurement strategy for procuring authorities. Used properly, robust procedures for needs assessments can encourage the effective value based procurement of innovative technology.

Needs assessments can be both long-term in analysing the priorities for procurement, as well as more focused, conducted in relation to a specific requirement.

The local regulatory, policy and healthcare environment will largely dictate procurement priorities and the place of innovation. However, implementing processes to conduct needs assessments can encourage the use of longer term decision making, as opposed to short term decisions taken to achieve quick results which can fail to take into account the range of technology available on the market or the long-term cost and benefit of technology across the healthcare system. Poor identification of needs may lead to products and services being procured which are sub-optimal as a result of not meeting the needs of clinicians and/or not taking into account future service delivery changes or poor interoperability with other procured products. These issues, if not addressed, risk incurring wasted time, effort and cost due to these types of inefficiencies.

Key issues in conducting a needs assessment

- Identify the needs of clinicians, patients and the population.
- Analyse the performance, efficacy and reliability of existing products and services.
- Consider needs on a short – medium – long term basis.
- Where appropriate, assess needs on a broad healthcare system perspective.
- What are the procurement options?
- What are the procurement priorities?
- What are the budgetary constraints?
- The role of HTAs is discussed in Part Four.

Understanding the market – conduct thorough pre-procurement market engagement

It is important for a health authority to engage with its supplier base prior to commencing a procurement. No or limited engagement can lead to a lack of market awareness of new products or a reliance on the dialogue stage of certain procurement procedures as a means of engaging with suppliers.

To achieve the procurement of innovative medical technology that provides purchasers with value for money, it is essential to incorporate a structured means of market engagement and horizon scanning into the management of procurement teams.

Part Two

The pre-tender phase

Conducting pre-procurement engagement can be used either in relation to a specific upcoming requirement, or can be used **flexibly by way of an ongoing interface with industry.**

The benefits of this include:

- Stimulating competition which can reduce the dependency on a small number of suppliers;
- Providing procuring organisations with information and insights which can be used to develop an informed and forward-looking procurement strategy. It can also reduce the tendency to rely on incumbents and help "level the playing field", as well as avoid requirements and specifications being based on or strongly influenced by the products and services provided by incumbents, thus mitigating any incumbency advantage;
- Managing market expectations – by engaging with a supplier base, and setting out procurement pipelines and the capabilities needed to deliver them, suppliers can be prepared for upcoming tenders, and officials can be better assured that those companies asked to provide products and services can meet the stated needs;
- Strengthening the relationship between industry and procuring authorities and providing the opportunity for smaller or new market players who may be responsible for placing new technology on the market to compete;
- Providing an opportunity for the health authority to sense-check its requirements, the feasibility of the requirements, the timescales in which they can be achieved and the capacity of the market to deliver. Procuring authorities can also use this opportunity to consult on whether splitting a contract into smaller contracts or lots to stimulate greater competition and the involvement of SMEs would be appropriate;
- Allowing the market to raise questions or challenge procurement approaches, thus minimising the risk of any legal challenges once the tender has commenced;
- Avoiding the need for long and complex procurement procedures which may be chosen where procurement or clinical teams are unsure as to the products available on the market;
- Allowing the formulation of appropriate, realistic and tailored requirements;
- Identifying and evaluating risks early and designing risk management strategies.

Set out below are some different means of conducting pre-procurement engagement which can be used either in relation to a specific upcoming requirement, or can be used flexibly by way of an ongoing interface with industry:

- **Detailed research** - in undertaking this research, whilst some of the medical and other experts involved may be internal to the procuring organisation, it may be appropriate to bring in external experts. For instance, trade associations can provide useful input into product development, as can some professional bodies.
- **Using structured market or supplier days** to test out thinking on requirements and outcomes prior to commencing the formal procurement process.
- **Market sounding approaches** - using questionnaires or interviews to gather information in the market or issuing consultation documents about specific opportunities, for instance by using a market sounding prospectus.
- **Communicating**, either through formal means such as EU Prior Information Notices (PIN notices) or equivalent means, such as press releases, websites or industry meetings to outline upcoming needs and tenders to the wider market;
- **Issuing an open invite** to industry to come forward with new technology and innovations.

Suppliers should not be afraid of participating in market engagement activities, but should encourage opportunities to increase the awareness by procuring authorities of the range of medical technology available.

Part Two

The pre-tender phase

Minimizing risk in pre-tender engagement

Appropriate consultation with industry is a main contributing factor in the smart procurement of value for money medical devices. However, pre-tender consultations should not be used in a way which could prejudice tender outcomes under either public procurement or antitrust rules. It is important that competition is not distorted by the participation of certain suppliers in any pre-tender engagement process, either in general terms or in relation to a specific procurement.

These risks should not arise if key compliance measures are observed, including:

- In instances where the conclusions of a pre-tender review could exert a material influence on future tenders, and above all where a potential bidder has been closely involved with any consultative process used to inform the specifications, then those conclusions must be shared with the whole sector.
- No supplier should be given an advantage – in the form of additional information – over another.
- Ensure that all suppliers are aware that any resulting procurement will be conducted competitively.
- Ensure that a proportionate number of suppliers are consulted which are commensurate with the market size. It is not essential to speak to every supplier but a suitably broad cross-section of suppliers, including SMEs, will provide valuable input.
- Resulting specifications or requirements should not be designed in favour of any one potential supplier.
- All information disclosed by a supplier should be treated confidentially and not disclosed to other suppliers. It should always be remembered that procurement legal regimes generally allow pre-tender engagement. The new EU regime, for instance, expressly allows a “preparation” stage on condition that processes are in no way distorted by such preparation. The WHO has used pre-tender engagement, for example in the context of its development of technical and quality specs for mosquito netting. What regimes do not allow is conduct lacking in transparency or any conduct which could allow a present or future tender procedure to become biased towards a particular bidder.

Outlining requirements – ensure the specification or required outcome is appropriate to the technology to be sourced – but don't over specify

Specifications should be drafted carefully to achieve a value based outcome whilst promoting innovation. It is necessary to strike a balance between clarity and flexibility. A narrowly drafted specification can result in a limited number of suppliers submitting a compliant proposal and a failure to consider innovative technologies and alternative solutions. Whilst these outcomes can be avoided with the use of broader specifications, procuring authorities need to take care to ensure that the requirements are sufficiently clear so that suppliers can participate in the procurement on an informed basis and submit responsive tenders which are evaluated against transparent and objective evaluation criteria.

Part Two

The pre-tender phase

The approach taken to drafting a specification will largely depend on the nature of the technology to be procured and the process used to procure it. For established, commodity-like technology which can be procured using simple, invitation-to-bid type procurement processes, it may be appropriate for the specification to be narrowly drawn. For more complex or fast-moving technologies, or where the procuring authority is requiring complementary service provisions, and/or where the authority is looking for suppliers to provide solutions, the needs of the authority are broader, and should focus on required outcomes, rather than detailed product and service descriptions. A statement of outcomes specifies the result to be achieved and opens up the possibility for suppliers to offer innovative solutions which can meet the procuring authority's needs in different ways, which can deliver improvements in quality and better long term value for money.

The role of stakeholders and KOLs – consult with the right people

A statement of outcomes specifies the result to be achieved and **opens up the possibility for suppliers to offer innovative solutions.**

Allowing sufficient preparatory time to develop an appropriate and focused specification and tender request should be a key priority for a procurement team. To achieve this, the procurement teams setting the parameters of a procurement need to ensure they have engaged with appropriate stakeholders. Procurement teams will only know that their specification is aimed at obtaining the latest and most effective innovative technology if they have consulted with specialized experts with relevant experience of the product area in question.

All procurement authorities should have a process for deciding the best way to identify the most appropriate clinicians and stakeholders. They need to be able, on a routine basis, to select a suitable KOL who should work from the outset in identifying experts who would be suitable individually to provide input into a specification and who would in combination form a suitably broad mix on a review committee to determine whether and how innovative products should be within the specification and what those products might be.

Appointment of KOLs could be from an established and easily accessible list of such KOLs, or as a result of the procurement team issuing requests for information to determine who is best placed. In the vast majority of cases involving medical devices, the most appropriate people will mean physicians, including consultants and surgeons. In many cases, however, it will also be advisable to consult with other categories of healthcare professionals. This might mean operating theatre administrators, surgical technicians, physiotherapists, anaesthesiologists or nurses. Patient groups may also provide valuable input. Often, a regulatory expert would be an appropriate participant.

The key for procurement teams is to ensure the right balance of specialisations and the right process for the conduct of that review. The purpose of a peer review is to ensure that specifications are checked by a sufficiently diverse range of experts. No one person can know everything about a product area, and over-reliance on certain individuals can lead to a loss of objectivity, over-reliance on a product type or an unfounded preference for an incumbent supplier.

The formation of a specification committee can achieve this balance. One of the functions of the KOL responsible for the make-up of the specification committee should be to define roles and to ensure that all disciplines relevant to the product area have an expert voice on that committee, including a blend of (i) internal staff from the hospitals connected to the procuring entity and (ii) external experts.

Part Two

The pre-tender phase

Ensuring the right processes are in place in order to assess the impact of innovation

Once a specification committee is set up with representation from a broad and diverse range of disciplines linked to the product area, and once members of that committee have clear roles and responsibilities in the development of the product specification, it is recommended that a protocol of the committee is established. All members should be aware of the purpose of the committee:

- It should be clearly stated that the overriding objective of the committee is to assist in designing a fair and comprehensive tender that is orientated toward best value (rather than price) and facilitates publication by the procuring authority of a set of well-rounded specifications which are responsive to the desired healthcare outcome.
- One of the fundamental aspects of that overriding objective is to ensure that specifications catch all ascertainable and available innovations – in other words, physicians and other stakeholders should understand that “product conservatism” or “clinical conservatism” is against the spirit and rules of the committee’s function.

Transparency should **inform all stages** of this process.

Suggested principles for the functioning of the committee include:

- All members should have an opportunity to have their views heard and recorded – it may be that a representative from each discipline could present to the rest of the committee, before specifications are drafted.
- Fair mechanisms for voting, decision-making and access to information should be implemented and observed to ensure objectivity and fairness.
- The aim of decision-making should be consensus, with majority voting being the benchmark.
- There should be defined stages for the assessment of specifications – with rotation of drafting and review roles between stages to ensure a diversity of perspective. For instance, industry, healthcare professionals and the procurement managers could each conduct a separate review of the specification.
- These defined stages should be agreed, set out in writing and observed – with a due record maintained of compliance with those agreed stages.
- Relevant KOLs must review and sign off all drafts – the committee should not be set up so that procurement teams take away lengthy research reports which inform specification documents which the broadly constituted committee then do not see.
- Transparency should inform all stages of this process.
- For complex product areas, it is recommended that committees have an extra stage of specification testing, where a draft specification is produced for general consultation by industry (even beyond representatives on the committee itself) before finalisation of the specification.

Part Two

The pre-tender phase

- All members of a specification review committee must take care to ensure that specifications are neither overly generic, nor weighted towards one product where this can be avoided.
- The priority on scope should be to avoid grouping together products which are unconnected in medical terms.
- Where a specification does cover a spectrum of product types, then it is likely to be advisable to divide it into product lots for a segmented procurement. A division into lots would accord with procurement policy and allow greater participation by SMEs. For healthcare technology, the decision on whether to adopt a lot system should be taken on medical grounds.

The main point for specifications is that it is critical for procurement teams to institute a plan for producing the specification and testing it. That plan should allow the transparent and objective consideration of all available research. Failure to do this can be a problem at later stages with unclear procurement procedures involving either the procurement of sub-optimal products or defective procurement procedures in legal terms.

Evidence of value and innovation – getting the right information

It is the role of clinical experts on specification committees to ensure that the procurement team is aware of the clinician team's findings on available and potential future technology options and their likely outcomes. Conversely, it is the procurement team's job to ensure due attention is paid to the clinical impact of technology. Above all, it is important that the selected requirements can be properly evidenced.

To ensure this reciprocal information flow works well, the following steps can be taken:

- Procurement teams should find out from medical specialists familiar with the area whether medical outcomes are satisfactory. Is the current device portfolio working for that condition?
- Is it a mature product area without obvious or predicted further developments? Are there manifest gaps in terms of medical efficacy, patient comfort and cost-effectiveness?
- Is significant innovation likely to overlap with the period covered by a particular procurement? Should this influence the period of a tendered contract? In most cases, the specification should allow for the possibility of contracts to be varied to accommodate appropriate innovation.
- Where available in relation to the medical area covered, horizon scanning and other market research tools should be checked to review the innovative landscape, although such information should always be sense-checked with the medical KOLs involved in the specification committee.
- Similarly, information derived from HTAs (discussed in Part Four) or other econometric tools must be used in a balanced way and be assessed and applied in accordance with the views of hospital-based experts.

It is the role of clinical experts on specification committees to ensure that **the procurement team is aware of the clinician team's findings** on available and potential future technology options and their likely outcomes.

Part Two

The pre-tender phase

Ensuring pre-tender review processes are legal

The comments in this section on specification review committees, like all comments in these guidelines, are informed by procurement laws. It is essential that the proceedings of specification committees observe the key principles of procurement law regarding transparency and nondiscrimination and also the prohibition of collusion under antitrust law. See also “Minimizing risk in pre-tender engagement” above for guidance on conducting compliant procedures.

However, it is equally significant to remember that such committees can be legally compliant if they adopt a number of simple measures. Excessive caution can be counter-productive. A remote and avoidable legal risk should not be adequate reason for refusing to conduct essential prior research and consultations which are essential for an effective procurement of appropriate medical technology.

Guidelines on the best use of the pre-tender phase

The five key aspects of pre-tender consultations can be summarized as follows:

- **Right timing** – procurement teams should ensure that mechanisms for assessing and finalising specifications are in place and operational more than a year before commencement of the competitive tender process.
- **Right people** – committees responsible should involve a balanced and cross-disciplinary representation of healthcare professionals who should be KOLs for that product class.
- **Right process** – the functioning of committees should be regulated to ensure legal compliance, but also to ensure consensus and sustained peer review.
- **Right evidence** – committees should assess HTA and horizon scanning information in the light of the views of medical experts.
- **Right record** – for every procurement, a record should be kept of the steps taken to ensure that the guidance in this section on the conduct of review committees is observed.

Part

Three

Choice of procurement approach



Part Three

Choice of procurement approach

Key learnings summary

- The choice of procurement approach should, where possible, be done on a tender-by-tender basis to ensure the approach is tailored to the products and circumstances in question.
 - Where a product category is likely to be advanced through innovation, flexible procurement processes involving negotiation will increase the likelihood that innovative and best-value technology will be procured.
 - In simple procedures, such as “invitation to bid” procedures or sealed bid procedures or the open and restricted procedures in the EU, there is no or limited legal scope for negotiation.
 - However, in most regimes globally, other procedures are evolving and are increasingly encouraged under legal regimes to favour focused procurement.
 - It is therefore essential for procurement authorities to understand the options open to them and not to implement simple procedures on a rigid or cursory basis or through excessive caution. Negotiated procedures are often workable and within the bounds of established law.
 - The choice of flexible procurement procedures in an evolving legal landscape is a critical area for procurement authorities to share amongst themselves.
 - The use of lots and variant bids are increasingly encouraged within procurement policy to foster innovation and allow participation by SMEs.
-

Part Three

Choice of procurement approach

Survey of available procedures

A procurement authority should, in all cases, both review the procurement options which are available to it under relevant laws and protocols and choose the option best suited to the technology which it wishes to obtain. In all cases, this will mean working out whether the innovative landscape is clear and predictable from the outset or whether it is likely to be difficult to foresee how technology will change. Factors which are relevant to this decision are:

- What is the nature of the requirements – for example, are the requirements for a readily identifiable and existing product, or is the procuring organisation looking for a solution based approach mixing the provision of products and services?
- What is the level of knowledge about the technology and related services – can a robust specification be clearly identified or would the solution be best achieved through dialogue?
- Does the technology currently exist on the market?
- What is the innovation cycle of the relevant technology?
- What are the number and type of the potential suppliers and what is the structure of the market?
- Internal resource capacity – for example, does the procuring organisation have sufficient manpower for a process involving dialogue or negotiation?
- Are there rigid timescales which need to be achieved (for example the imminent termination of a contract), or does the procuring organisation have more flexibility?
- Where the product scope or the value of the product is difficult to ascertain at an early stage, negotiation will allow for due consideration of non-price factors and therefore a more precise assessment of value.
- Procedures involving innovative technology are likely to require a degree of flexibility in ascertaining the technology solutions which are available and required. In cases where extensive change through innovation is not anticipated, there may be no need to pursue a negotiation based procurement. In these cases, however, it will still be necessary to ensure value-based procurement by, for example, actively engaging with appropriate stakeholders.
- To a greater or lesser degree, legal regimes regulating public procurement will permit negotiation either generally or in set procedural formats. In all cases, it can be expected that legal regimes will permit negotiation only where engagement between the authority and the bidders is transparent and even-handed. Any recourse to negotiation, and any protocol governing methods of negotiation, should be conducted or drafted to respect these principles. However, it is a mistake to avoid negotiated solutions, which are increasingly accepted and promoted by legal regimes, on a cautious basis, since this can lead to unreliable procurement outcomes.

A procurement authority should, in all cases, both **review the procurement options which are available to it under relevant laws and protocols** and choose the option best suited to the technology which it wishes to obtain.

Part Three

Choice of procurement approach

Procedures not involving negotiation

By definition, an Invitation to Bid or Request for Quotation procurement cannot involve negotiation. These processes are all based on the sealed bid, which cannot be withdrawn. Such procurements can only be about price and will often be unsuitable for medical devices. Open procedures under EU rules (where anyone can bid) or restricted procedures (where only candidates who pre-qualify are invited to bid) can allow value-based procurement, but do not allow substantive negotiation. Requests for clarification of the specification are permitted, but should not involve fundamental renegotiation of the specification.

Procedures involving negotiation

The scope for using negotiated procedures will depend largely on the relevant legal and regulatory regime, and to the extent that those apply, the role of negotiation may be significantly constrained and regulated. Some procuring authorities can approach negotiated procedures with caution based on the assumption that negotiation introduces partiality, lack of transparency or risks information being shared with some bidders but not with others. However, negotiated procedures can be effective in sourcing innovative medical technology. Negotiations allow the benefits of non-price quality features to be addressed and given due consideration. Another benefit of negotiation is that it can be used to provide pressure points to achieve value across a range of measures.

EU rules acknowledge that there is a greater need for procuring authorities to have additional flexibility to choose a procurement procedure with provides for negotiations.

Different approaches can be taken with negotiated procedures, but the historic concerns with this model can be well-managed and eliminated. Negotiations can be simultaneous or sequential. In simultaneous negotiations (such as the EU competitive dialogue procedure), the procuring authority engages with several suppliers at the same time to learn about market capabilities, refine specifications and achieve solutions which meet the authority's requirements. A procuring authority needs to ensure that it has sufficient resource for this approach since this can be time consuming. Authorities need to ensure equal treatment by providing the same information to all bidders at each stage of the procurement, including any changes to the requirements to allow each supplier to respond, prior to any down-selection being made.

In sequential negotiations, proposals are first assessed and ranked from most to least attractive. The supplier with the highest ranked proposal is invited to negotiate and where agreement is reached, it will be awarded the contract. Lower-ranked proposals are considered only if negotiations with higher-ranked suppliers fail. This approach can be more time efficient, although it can be less transparent and can be less effective in receiving a range of solutions for the authority's requirements.

Procedures involving negotiation under the EU rules

Until recently, the EU rules allowed for a negotiated procedure (with or without an advertised process) only in limited circumstances or for a structured competitive dialogue procedure for complex contracts where the specification cannot be drawn up in advance.

However, in 2014, the EU rules were reformed with the EU acknowledging that there is a greater need for procuring authorities to have additional flexibility to choose a procurement procedure which provides for negotiations. The EU found that an increased use of negotiated procedures enhances cross-border trade.

Part Three

Choice of procurement approach

Procedures not involving negotiation

One of the changes of the revised EU procurement rules is to extend to four the types of allowable procedure with an element of negotiation. The four types of allowable procedure are as follows:

- The competitive dialogue procedure remains: this is summarized in a separate box.
- There is a new competitive procedure with negotiation: this has some similarities to the competitive dialogue procedure and can be used in a wide range of circumstances, including where innovation is involved. Unlike in competitive dialogue, it requires that the procuring authority can specify the required characteristics of the goods or services in advance of the competition.
- A separate category of innovation partnership: this is summarized below.
- Negotiated procedure without notice: this procedure which allows for single-supplier sourcing without a competition applies in only exceptional circumstances and is unchanged from before.

An existing procedure: competitive dialogue

A process to allow procuring authorities to “identify and define the means best suited to satisfying their needs” through successive stages of negotiation with gradual down-selection until final bids are requested. Competitive dialogue allows bidders to propose their own solution to address the requirements of the authority, rather than responding to a common specification.

The typical stages of a competitive dialogue are:



Part Three

Choice of procurement approach

A new procedure: innovation partnerships

Similar to any competitive procedure with negotiation, an innovation partnership is available where innovative products are required and the need for the services or works cannot be met by purchasing existing products.

The innovation partnership contemplates the award of a phased contract to cover all stages of product development from R&D, prototyping, and eventually the purchase of the resulting products or services.

The partnership can stop at any stage of the R&D, manufacturing and commercialisation cycles.

This means that partnerships are possible with different partners for the same innovative product set. The structure and timetable of the partnership must reflect the complexity of the innovation.

The general drawback for any procedure containing negotiation is complexity and potential delay. Where applied correctly, however, this is far outweighed by gains in informed and appropriate procurement, resulting in enhanced value.

Procedures involving negotiation: procuring for solutions

A form of highly sophisticated procedure involving negotiation is procuring for solutions. Although procuring for solutions is new and complex, it may have enormous potential to encourage the focus on innovation in healthcare procurements.

Procuring for solutions targets a care outcome as the basis for a tender award on the basis of a construct. A construct is a grouping of products that all deal with the same medical condition yet vary slightly according to characteristics of the patient. Effectively, therefore, bidders are asked to provide information on a whole tool-kit to cover that condition. This involves complex specifications and value-assessments, but ensures that the full innovative product landscape is accounted for at all stages.

The role of centralized procurement

In many jurisdictions, healthcare procurement is conducted on a centralized basis. Centralized procurement can take various forms:

- The health ministry or its central agencies may purchase for all hospitals regionally or even nationally.
- Hospitals may procure through buying groups or hubs.
- National or regional procurement tends to be conducted under frameworks, i.e. umbrella appointments where the actual procurement is done subsequently through call-offs or mini-competitions under the central framework.

Although procuring for solutions is new and complex, it may have enormous potential to encourage the focus on innovation in healthcare procurements.

Part Three

Choice of procurement approach

- Whatever the format, centralized procurements typically involve the use of enlarged specifications, arguably in some cases rolling more than one product area into the same procurement exercise for administrative convenience.

Centralized procurement can provide benefits to health authorities in the form of simplified procurements, budgetary convenience, enhanced purchasing power and procurement consistency. However, when adopting centralized procurement approaches, procuring authorities should also be mindful of not fostering a commoditized procurement with limited access to innovation and SMEs.

Lots

The use of lots can assist innovation as well as encouraging the participation of SMEs.

Lots is the term used when a larger requirement is broken down/compartimentalized into smaller, grouped requirements. Grouping usually is on the basis of similar products/services. The use of lots can assist innovation as well as encouraging the participation of SMEs. Indeed the recently revised EU 23 procurement Directives actively encourage procuring authorities to divide large contracts into lots in order to facilitate SME participation, and require procuring authorities to justify why a contract was not broken down into lots – the “apply or explain” principle.

Whilst the use of lots promotes SME participation and avoids the “winner takes all” approach, procuring authorities need to be mindful of the circumstances in which lots may not be appropriate. Dividing contracts into many or poorly constructed lots can dampen competition (particularly where a procuring authority limits the number of lots which can be awarded to one supplier), and can disincentivize suppliers from proposing innovative solutions and risk reward mechanisms. It can also result in more difficult and expensive contract management.

Variants

Innovative bids can be encouraged by allowing suppliers to submit variants to the core or standard specification. In many jurisdictions, it can be unclear whether the procuring authorities have any latitude to permit variant bids, i.e., where a feature of the bid would represent a modification of the technical requirements.

The revised EU procurement Directive expressly promote the use of variant bids in the context of innovation: “Because of the importance of innovation, contracting authorities should be encouraged to allow variants as often as possible”. However, the EU requires certain safeguards, namely that the authority shall state whether variants are permissible, the minimum requirements for variants and that the chosen award criteria can be applied to variants meeting those minimum requirements.

In allowing variants, procuring authorities need to be mindful of running a procurement which is robust, transparent and grants equal treatment to all suppliers. Allowing a variant bid should not be used as a mechanism to change fundamentally the requirements of the procuring authority; instead a variant should be permissible to the extent that it provides an alternative solution to meet those requirements.

Part Three

Choice of procurement approach

The move away from simple commodity provision to a **service model** has encouraged **changes** in the corporate formats of procurement solutions.

Alternative delivery models

In some cases, the structure of transactions in procurement contexts is changing. The move away from simple commodity provision to a service model has encouraged changes in the corporate formats of procurement solutions. Increasingly, medical device suppliers provide not only goods but services, whether linked to the devices or more broadly to a range of services around a particular health issue, regardless of care setting, or to a hospital client's business and operational needs.

This is increasingly called the "managed service" model. Typically the managed service model means that the supplier will supply, maintain, service and provide all equipment and consumables for specific clinical needs, and deliver all associated services. This is generally done within the context of a risk sharing model where many of the costs and risks are largely borne by the supplier, reducing significantly the risks of the procuring authority.

Whilst such models can be structured in a variety of forms, their use often means that the specification of a procurement may contain different forms of product and service. Not all of these may be easy to pinpoint at an early stage. Such models also require flexibility in terms of the corporate structure, with joint ventures and consortia being used more frequently. Expanding deal options of this nature may increase the need for negotiation-based procedures.

Part

Four Value



Part Four

Value

Key learnings summary

- The United Nations and procurement agencies in a number of major jurisdictions recommend that value be determined by a mixture of price and non-price factors and that price factors themselves should reflect the whole technology lifecycle.
 - Procuring for value means looking at all aspects of medical technology. Even where the acquisition price seems high, the effect on health outcomes and general cost-effectiveness may yield net gains in broad value terms.
 - It is not enough just to understand value. Processes need to be adopted to ensure the practical application of a value-based approach. Decision-making bodies should comprise a diverse range of stakeholders, including medical experts and end-users, which will ensure transparency and fairness.
-

Decision-makers in award procedures must be drawn from a multi-disciplinary range of complementary but diverse experts.

How to implement value-based procurement

For every medical device procurement, processes need to be implemented to capture a value-based assessment, which means the right intensity of review, by a sufficient range of experts, with reference to a sufficient quantity of relevant information.

Decision-makers in award procedures must be drawn from a multi-disciplinary range of complementary, but diverse experts, similar to the range of specialisations which should determine specifications at the pre-tender stage. Tender documents should set out the full detail of value-based criteria to be applied in an award procedure and governance procedures must be implemented to ensure that all such valuebased criteria are applied in the award assessment. Cross-checks of award decisions should be made by all the specialists who feature in the award procedure according to a pre-agreed peer-review protocol.

The use of multi-disciplinary decision-making procedures can be expected to have two positive effects. First, they will encourage the use of focused and informed awards based on consensus. Second, such governance procedures will also serve to lend greater credibility to procurement decisions and reduce accusations of misspent public funds, corruption and bias.

Part Four

Value

Health Technology Assessments (HTAs)

HTAs are increasingly used by procuring authorities when sourcing medical technology. The purpose of an HTA is to provide evidence to justify the purchase of best-in-class medical technology when tight budgets need to be balanced. Information derived from an HTA can be used both to inform the drafting and design of the tender specification as well as in negotiating a contract with a supplier.

What is an HTA?

HTA is an umbrella term reflecting a wide approach of methodologies. Jurisdictions and health authorities vary in their prescribed methods for conducting an HTA. However, in general terms an HTA is all about combining evidence of clinical effectiveness and economic benefits (usually expressed as some variant of cost). It is meant to serve as medical evidence for an economic purpose, i.e. a multi-disciplinary bridge between medical practice and policy-making or budget decisions.

An HTA can be a complex appraisal which should assess considerations of safety, efficacy (or better, "real-world" effectiveness), innovation and ideally comparative (or "incremental") cost-effectiveness, along with factors of social, legal and ethical relevance. It should address the following questions:

- Is the technology effective and in what ways?
- How does it compare with existing or other technology?
- What are the benefits of the technology – for clinicians, patients and the healthcare system?
- What are the costs of the technology? An HTA should correlate to value – all aspects of value should be included in an HTA. An HTA may refer to measurements of economic impact – e.g. incremental cost-effectiveness ratios (ICERs) or quality-adjusted life years (QALYs), which seek to link medical change to effects on costs, and the duration and quality of relevant health conditions.

Whilst HTA information can represent high-calibre and useful evidence of a device's value, there can be cases where the evidence provided by an HTA will not have a sufficiently broad perspective. Regulatory or HTA information may not give the full picture of a device's true impact on healthcare outcomes.

Often, HTA information may have been generated by procurement healthcare officials without reference to unbiased experts involved in clinical practice. Thus, there is a risk that a circular and self-validating process of calibrating expenditure is followed without due regard to expert opinion as part of a sense-checking procedure or cost-containment tool. Other challenges include the inability of an HTA to assess incremental innovations, and a lack of consistency arising from the use of different targets and objectives to measure products and suppliers. Many national HTAs may not provide the data required at hospital, local or regional level.

Regulatory or HTA information may not give the full picture of a device's true impact on healthcare outcomes.

Part Four

Value

Thus HTA or similar information can be an excellent source of evidence to inform procurement decisions. It must, however, be used wisely to account for clinical reality, depending on the type of device, the type of medical procedure, and the history of spending in relevant locations within a specific, defined region. When using HTAs as part of a procurement strategy, it is important to consider:

- That to the extent feasible, the assessment focuses on real-life data.
- Basing the assessment on clinical outcomes and involving clinicians in the process, as well as their scientific and professional bodies.
- Ensuring consistency of approach in the objectives and performance indicators used in the assessment.
- Whether the assessment is appropriate for the specific procurement – does it measure the relevant outcomes required for the procurement and/or the values which are important to the procuring authority? Rather than using a national HTA, would it be more appropriate to conduct an HTA at a hospital or a local level?

The use of value-based award criteria **should be routine in medical device procurement.**

Guidelines on how to achieve value-based procurement

Recommendations for procurement authorities to utilize in order to maximize the value of health technology procurements are as follows:

- The use of value-based award criteria should be routine in medical device procurement (as opposed to simplistic recourse to procurement based on lowest price). For EU procurements, this would mean a policy of applying MEAT criteria. For other jurisdictions, this would be “best value for money” procurement or the nearest equivalent.
- Even though procurement authorities may be under no legal obligation to implement MEAT or best value criteria, these should be normalized as the most appropriate method of procuring innovative healthcare technology.
- Award criteria should be verified against value-based checklists. These checklists can be consulted in advance with industry.

Part Four

Value

The relative weightings of cost and non-cost criteria and sub-criteria should be transparent and **cost criteria should never exceed 50%.**

- Within the MEAT/best value award criteria as set out in tender documentation, cost and non-cost criteria should be clearly delineated.
- The relative weightings of cost and non-cost criteria and sub-criteria should be transparent and cost criteria should never exceed 50%.
- Award criteria should not be so prescriptive that innovative solutions are penalized. There should be incentives for innovation.
- Decision-makers throughout the procurement process from design to award should involve a diverse range of stakeholders, which should include medical experts and other end-users.
- Decision-makers should have the right to review and amend criteria in advance of the release of tender documentation and, subsequently, to review award decisions to guarantee the application of award criteria.
- For each tender, compliance with this value-based policy should be recorded. Where procurement authorities choose to purchase according to price or where over 50% of the award weighting is accounted for by price, such cases should be exceptional and the reasons for this choice should be set out in a written report.
- Within each national jurisdiction, fixed value protocols can be agreed between industry, healthcare KOLs and procurement authorities to ensure certainty and a value-based policy.

Part

Five

Post-award



Part Five

Post-award

Key learnings summary

- The terms and conditions on which suppliers contract with a procuring authority are central to the procurement process and should be carefully considered at the outset of a procurement process. Creating a contractual structure which incentivizes suppliers to innovate and allows innovations to be introduced during the lifetime of the contract is the optimum approach.
 - Procuring authorities should view each procurement as a learning experience, both in terms of the procurement process used and the longer-term implementation of the contract.
-

Contractual incentives

Contractual incentives, whereby the procuring authority and the supplier can share the benefits can encourage suppliers to develop innovative solutions to meet changing needs. Contractual mechanisms include, for example, risk and reward sharing obligations for patient outcomes achieved or for efficiencies created.

Change control mechanisms

Since legislative requirements often prevent unplanned substantive changes being made to the contract or to the scope of the services or products to be supplied, procuring authorities should also ensure that change control mechanisms are contemplated at the time the contract is being procured so that changes can be incorporated into the contract.

Relevant factors for procuring authorities to consider include:

- Medical device technology develops quickly, often in 18-36 month product life cycles. Often innovation is incremental, but may also be break-through. Incremental innovation is valuable in that it can lead to better patient outcomes or efficiency.
- It is essential therefore to build the contract in a way that anticipates change and the opportunity for introducing new technology.
- A simple approach is to enter into contracts with a term of limited duration, recognizing the short product life-cycle.
- On the other hand, a longer term may be useful if the tender is requesting a major investment or risk-sharing arrangement from the suppliers.
- Whether specific contract terms relating to introduction of new technology can be included within the contract.

Part Five

Post-award

Monitoring and review

Signing of a contract with a supplier is only the beginning of the relationship. It is important for a procuring authority to review the procurement process used and assess:

- Was the procurement process suitable for the products or services procured?
- Did the authority have sufficient resources to manage the procurement?
- Was the pre-tender phase effective in raising awareness in the market and informing the authority of products and services available?
- Was pre-tender consultation with industry effective? How could it be improved?
- Did the products and services procured, and the manner in which they were procured, meet the needs of clinicians and patients and achieve the desired healthcare outcomes?
- As part of this exercise, it is important to consult with suppliers who participated in the process and seek their feedback.
- In addition, a procuring authority should also monitor and review on an ongoing basis the implementation of the contract and effectiveness of the products and services procured.

Conclusion

Procurement of medical technology, done properly, and with an eye toward factors other than short-term price, can greatly enhance value and efficiency in the health care system. Procurement should thus emerge as a partner to innovation and value in ensuring sustainability, access and quality in the Irish health care system.

This report demonstrates how best practices are put to work at various stages of the innovative procurement process: from pre-procurement processes that are essential to maximize fairness and useful input to allow for the most up-to-date technologies and concepts of value to be utilized, to capturing adequately these concepts in technical specifications written by committees of end-users, to award and post-award processes that help to ensure flexibility and fairness. They also present a robust palette of policy choices to enable greater utilization of innovation procurement, to enhance outcomes and value and to identify where there are opportunities to procure for solutions rather than products. To achieve these objectives, we would encourage the adoption of the best practices outlined in this paper by all stakeholders.

Procurement can be a powerful tool that, when utilized properly, enhances value and innovation in the Irish Health care system. The goal of innovative procurement is to maximize public purchasing power to enable patients to receive the best, most cost-effective, life-saving and innovative treatments across all phases of health care. If utilized judiciously, procurement can be a tool to create efficiency and quality rather than just cut costs.

IMSTA view this paper as a further step in our commitment to support health care system performance, access, quality and sustainability and greater social and economic development. We continue to believe that the continued meaningful engagement between industry, policy makers and stakeholders holds the most promise for improving the Irish Health Care procurement processes and to further enhance the value within the health care system.

Recommendations

Appoint Procurement Committees

Procurement Committees to oversee needs assessment, market engagement, specification generation and the most appropriate procurement processes are essential to maximize public purchasing power to enable patients to receive the best life-saving, most cost-effective and innovative treatments across all phases of health care. In most, if not all, cases a suitable key opinion leader (KOL) with clinical experience of using relevant technology should be appointed to chair a procurement committee.

Procurement committees should comprise multi-disciplinary teams which, in the vast majority of cases involving medical devices, will mean physicians, often including consultants and surgeons, biomedical / clinical engineering, medical scientists and other applied healthcare professionals. In some cases other stakeholders and patient representatives should be consulted.

Standardise Medical Technology Evaluation

The broad diversity, rapid innovation cycle and unique nature of medical devices presents a challenge for gathering comparative clinical and health-economic data for all medical devices. While Health Technology Assessments (HTAs) are used by procuring authorities when sourcing medical technology, they may not always provide the data required at hospital, local or regional level. Studies which examine costs and benefits only at hospital level may be commercially useful to the hospital but will not necessarily address the impact on the broader healthcare system. Therefore, we recommend a multi-disciplinary Professional Evaluation Group be established, reporting to the Procurement Committee.

Facilitate and Adopt Innovation

Harnessing innovation has the potential to improve the health, well-being and economic productivity of the population and slow the growth in the cost of care. Funding innovation through pre-commercial procurement is a tried and tested process which challenges industry to come up with solutions for identified healthcare problems. Developing a guide to commissioning for innovation of medical devices, linked to unmet health needs identified by the National Clinical Programmes should be considered as a priority for the health service.

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